

REMARKS

This amendment responds to Office Action of June 23, 2009.

Rejection of Claims 15-22 under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 15-22 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Independent Claim 15, has dependent Claims 16-22. The Examiner asserts that according to Claim 15, water is added to the vitamin A pro-liposome and only the mixing or vibrating is done before usage, yet the specification at page 7, lines 22-23 state that water is added before usage and the two components are then mixed or vibrated. The Examiner has deemed this to be new matter. Claim 15 has been amended to clarify that water is added before usage and the combination of water and Vitamin A Pro-Liposome are then mixed or vibrated. No new matter has been added by these amendments. The applicant respectfully requests the Examiner to withdraw the rejection of Claims 15-22 in light of the amendment to Claim 15.

Rejection of Claims 7 and 9-22 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 7, and 9-22 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Office Action asserts that it is unclear how a liposome can be formed with poloxamer alone. Claims 7 and 9 have been canceled.

Independent Claims 10 and 15 have been amended to remove the compound poloxamer. Accordingly, independent Claims 10 and 15 and their dependent claims should no longer be deemed as indefinite. The applicant respectfully requests the Examiner to withdraw the rejection of Claims 10-22 in light of the amendment to Claims 10 and 15.

Rejection of Claims 7 and 9 under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 7 and 9 under 35 U.S.C. § 103 (a) as being unpatenable over Lee et al. (US 2003/0118616), Modi (US Patent 6,214,375), and Garriety (US Patent 6,045,821). Claims 7 and 9 have been canceled.

Rejection of Claims 7 and 9-22 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 7 and 9-22 under 35 U.S.C. § 103 (a) as being unpatenable over Payne (US Patent 4,744,989), by itself or in combination with Lee et al. (US 2003/0118616), or Keller (US 6,610,322) or Cole (US 6,544,531) or Meybeck (US 5,034,288) by themselves or in combination. The Examiner alleges that Payne teaches proliposomal formulations and a method of preparation containing biologically active agents by dissolving phospholipids in an organic solvent and coated on carrier material. The Examiner acknowledges that Payne does not teach vitamin A as the active ingredient. The Examiner alleges that the Lee, Keller, Cole, and Meybeck references each teach the routine use of vitamin A in either liposomes or proliposomal compositions.

As Claims 7 and 9 have been canceled, only Claims 10-22, of which Claims 10 and 15 are independent, are presently at issue. Independent Claims 10 and 15 both recite that the content of Vitamin A is 0.2-40%, and that the support substance is 1-80%, with the remainder being the lipid ingredients, buffer agent and water. The Payne reference merely discloses a method for preparing liposome precursors which include dissolving a predetermined amount of at least one liposome amphipathic lipid, optionally a biologically active compound, and optionally at least one adjuvant, in an organic solvent. The organic solution is then applied to a carrier material. (Col. 4, lines 20-27). Nowhere in Payne is vitamin A disclosed as a biologically active compound, much less disclosed for use in preparation of a vitamin A liposome comprising 0.2-40% of vitamin A, and 1-80% of the support substance. Even when combined with other references

which Examiner alleges disclose the use of vitamin A, a person having skill in the art would not be motivated to arrive at the claimed range of 0.2-40% of vitamin A, and 1-80% of the support substance in conjunction with the method disclosed in Payne for preparing a liposome, wherein the addition of a biologically active ingredient is at most, optional. The claimed ranges in Claims 10 and 15 of 0.2-40% of vitamin A, and 1-80% of the support substance are technical features which related to the stability of Vitamin A, which are not of concern in Payne.

Furthermore, the method of preparing vitamin A liposome according to the present application is significantly different from the method disclosed in the Payne reference. In the present invention, the vitamin A Pro-Liposome is prepared by a fluidized bed method, freeze drying method, or spray-drying method. In contrast, Payne discloses that components such as phospholipid, cholesterol, and drugs are dissolved in an organic solvent such as chloroform to form a lipid solution. Water-soluble components such as glucose or sorbitol are placed in a rotating flask to which lipid solution is added in several batches. The solvent is removed under vacuum from the rotating flask until all the lipid solution evaporates. The result in Payne is that the phospholipid, cholesterol and drugs are coated on the surface of the water-soluble components through the evaporation of the organic solvent. One having ordinary skill in the art would not be motivated by the teachings in Payne to use fluidized bed, freeze drying, or spray-drying methods of the present invention.

The applicant requests that the Examiner enter this amendment because the amendment puts the application in condition for allowance as provided in 37 CFR 1.116(b)(1). The Applicants request that the Examiner withdraw the rejection of claims 7, 9-22 and allow the application.

Respectfully submitted,
Erickson Law Group, PC

Attorney Docket No. 6480P0010US

By: /Randall T. Erickson/
Randall T. Erickson, Reg. No. 33,872

Erickson Law Group, PC
1749 S. Naperville Road, Suite 202
Wheaton, IL 60189
(630) 665-9404
Customer No. 41528